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10/719,407	11/21/2003	Edwin R. Scott	15942.1	3344

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,407	SCOTT ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *24-27 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,28-38 and 40* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *DETAILED ACTION*.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12-23,28, drawn to a compression garment.

II. Claims 24-27,39, drawn to a method for manufacturing a compression sleeve.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions group I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case a compression garment can be used to practice another different process.

3. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with **Tangren Dana on 7/27/05** a provisional election was made without traverse to prosecute the invention of Group I, claims 1-23,28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-27,39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claim 13** recites the limitation "the backing" in line 1, page 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1,2,10-12, rejected under 35 U.S.C. 102(a) as being anticipated by Hall US.

9. **As to claim1, Hall et al. discloses** a compression garment **(col.4 lines 14-15)** for compressing a portion of a body of a patient, the compression garment comprising: a garment body **(fig.1, 1)**: an outer layer **(fig.3, 14)**; an inner layer **(fig.2, 22)** secured to the outer layer, the inner layer at least partially

bounding a channel **(fig.1, wearer's leg is considered to fit in a channel)** adapted to receive a portion of a body of a patient **(col.4 lines 66-67),** the inner layer comprising: a backing **(fig.2, 22)** comprising a woven fabric sheet or a perforated polymeric sheet **("fabric", col.5 lines 44-45)** having an interior surface **(surface facing the channel, fig.2 , 22)** facing the channel; and a plurality of spaced apart pressure projections **(fig.2, 23 col.5 lines 43-45, pressure causes 23 to extend out of the fabric, therefore acts as a pressure projection or capable of providing some compressive pressure)** extending from the backing toward the channel, the pressure projections being integrally formed with or mounted on the backing **(col.5 lines 43-45)**; the plurality of spaced apart pressure projections bounding a plurality of spaced apart recessed flow path **(space between 23, see fig.2)** and a layer of compressible cushioning **(fig.3, 15)** material disposed between the outer layer and the inner layer.

10. **As to claim 2, Hall discloses** a compression garment as recited in claim1, wherein the garment body comprises a tubular sleeve **(see fig.1 disclosing a tubular sleeve)** adapted to receive an arm or leg of the patient.

11. **As to claim 10, Hall discloses** a compression garment as recited in claim 1; wherein the inner layer does not comprise a polymeric foam **("fabric" col.5 line 45)**.

12. **As to claim 11, Hall discloses** a compression garment as recited in claim 1, wherein the garment body has an interior surface **(facing the channel)** and an exterior surface **(opposite to the interior surface)** with a maximum non-compressed thickness extending there between in a range between about 0.5 cm and about 2 cm (note: applicant discloses compression garment comprising varying thickness on page 5 of the disclosure, therefore, the rage is not considered critical **(see col. 5 lines 41-49).**

13. **As to claim 12, Hall discloses** a compression garment as recited in claim 1, wherein the outer layer is comprised of a sheet of woven fabric material **(spandex is considered an elastic synthetic fabric, see col.5 lines 15-18).**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4,5,6,9, 13- 18,20,21,40 rejected under 35 U.S.C. 103(a) as being unpatentable over Hall US Patent 6,520,926 B2.

15. As to claim 3, Hall does not disclose a compression garment as recited in claim1, wherein the backing comprising the woven fabric sheet and the pressure projections are woven into the woven fabric sheet, and **as to claim 6, Hall does not disclose** a compression garment as recited in claim 1, wherein the pressure projections are sewn or secured by an adhesive to the backing, **as to claim 14, Hall disclose** a compression garment as recited in claim 13, wherein the pressure projections are integrally woven into the woven fabric sheet, **as to claim 16, Hall disclose** a compression garment as recited in claim 13, wherein the pressure projections are mounted onto the woven fabric sheet, **as to claim 17, Hall disclose** a compression garment as recited in claim 13, wherein the pressure projections comprise brushed cotton, a brushed polymeric material, woven fabric, or piled fabric **however applicant stated on page 7, 0022 that the projection can be separately mounted onto backing such as by stitching, tape, adhesive, Velcro,**

Fastener, or the like. Therefore, how the projections are mounted to the backing does not seem to be critical. Hall discloses the microdots are "joined under heat" to the backing (col.7 lines 46-48), where "Joined" is consider broader recitation of securing means. With lack of criticalities regarding a particular securing means is considered superior than others, it would have been obvious to considered the securing means of the projections to the backing as disclosed by Hall is considered to meet claimed limitation.

16. **As to claims 4 and 15, Hall does not disclose** a compression garment as recited in claim 3, wherein the inner layer comprises a corduroy fabric. However, application stated on page 7 0022 that the backing can comprise any breathable, woven fabric material or any other type of breathable material such as perforated polymeric sheets. Therefore, Hall's inner layer of fabric construction (col.5 line 45) would consider meeting the claimed limitation.

17. **As to claim 5, Hall does not disclose** a compression garment as recited in claim 1, wherein the pressure projection comprises a plurality of elongated ribs. However applicant has not established criticalities why elongated ribs are favored over spread apart projections as disclosed by Hall. It is well known in the art that pressure projections can come in wide variety of sizes and shapes. Therefore, it would have been obvious to consider a particular pressure projection required by the applicant as a matter of design choice.

18. **As to claims 9 and 20, Hall does not disclose** a compression garment as recited in claim 1, further comprising a plurality of compression straps, **however teaches the supports may include fasteners such as hooks, zippers, buttons and the like (col.7 lines 55-57)**, and straps are conventionally known in the art as a form of fastener used to fasten pressure sleeves and orthopedic

braces. Therefore, it would have been obvious to consider fasteners taught by Hall as an alternative or equivalent securing means.

19. **As to claim 13, Hall disclose** all claimed limitation including a plurality of spaced recessed flow paths (fig.2, spaces between adjacent microdots 23) except for a layer of resiliently compressible foam (see fig.7 reference object 96) material disposed between the outer layer and the inner layer, **However, applicant has stated other cushioning means including conventional padding, fabric padding such as the all in one moldable fabric can be used as an alternative to foam (page 6, 0020), and Hall teaches elastomeric cushioning layer (fig.3, 15) which is considered to meet the claimed limitation since this layer is capable of providing cushioning surface . Halls does not disclose** means for constricting at least a portion of the body when the body is in the at least substantially tubular configuration, **however teaches the supports may include fasteners such as hooks, zippers, buttons and the like (col.7 lines 55-57)**, and straps are conventionally known in the art as a form of fastener used to fasten pressure sleeves and orthopedic braces. Therefore, it would have been obvious to consider fasteners taught by Hall as an alternative or equivalent securing means.

20. **As to claim 18, Hall discloses** a compression garment as recited in claim 13, wherein the pressure projections do not comprises polymeric foam **("silicone" col.7 line 46).**

21. **As to claims 21,40, Hall does not disclose** a compression garment as recited in claim 3, further comprising a tubular compression sock comprised of a resiliently stretchable material that can be selectively pulled over the garment body, however applicant stated on page 14, 0038 that sock, one or more compression straps, inflatable bladders are considered mans for providing constricting at least a portion of the body. As discussed above, fastening means disclosed by Hall is capable of selectively constricting the sleeve.

Claims 7,8,19, 21,28-38,40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hall US Patent 6,520,926 B2 in view of Reid US Patent 6,656,141 B1

22. **As to claims 7, 19 and 8, limitations respectively "a cover layer" and "a sheet of resiliently stretchable material",** Reid teaches an inner lining ("cover layer" of Spandex. The lining covers the radially inward tips of pressure projections (fingers) where the layer is intended for comfort and cleanliness and will be formed from any suitably soft, relatively thin material which allows the resilient fingers/projection to apply pressure to the body part surface **(col.6 liens 15-20).** Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the sleeve of Hall in view of Reid in order to add a cover layer for the purposes of allowing comfort.

23. **As to claims 21,40, Hall does not disclose** a compression garment as recited in claim 3, further comprising a tubular compression sock comprised of a resiliently stretchable material that can be selectively pulled over the garment body. **Reid teaches secondary sleeves (fig.5A, 40) may come in various sizes to be used for pressure adjustment (col.10 lines 49-50). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the sleeve of Hall in view of Reid in order to provide compression sock for the purposes of applying adjustable pressure along the length of the sleeve.**

23. **As to claims 28,29,33, 35, Hall disclose all claimed limitation including** a terminal portion **(the two openings of the sleeve to slide the body part)** having a proximal end and a distal end mounted at an end of the sleeve, the terminal portion having an interior surface **(surface facing the channel)** encircling a channel adapted to receive a hand or foot of the patient, except **for** a plurality of compression straps connected to or removably disposed on the exterior surface of the sleeve, each of the compression straps being configured to selectively constrict around the sleeve when the compression sleeve is in the

substantially tubular configuration, or a tubular compression sock comprised of a resiliently stretchable material that can be selectively pulled over the body **(underlined limitations are taught by Hall in view of Reid, see rejection for claims 9,20,21,and 40)**; the terminal portion being configured to apply progressive pressure along the length of the hand or the foot when received therein without the use of an external pressure force, wherein the progressive pressure increases the pressure from the proximal end to the distal end of the terminal portion. **Reid teaches separation of individual fingers/pressure projection is an advantage particular in that it allows for more precise control of pressure and pressure gradient applied to the body surface (col.6 lines 45-50). Reid additionally disclosed that sleeves capable of increasing or decreasing pressure gradient are well known in the art (col.2 lines 10-25). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the structure of pressure projection in view of Reid whose teachings suggest certain construction of the pressure projection would capable of yielding the required increasing pressure gradient from one end to the other end of the sleeve as claimed by the applicant.**

24. **As to claim 34, Hall discloses** a compression garment as recited in claim 33, wherein no compression straps are mounted on or encircle the terminal portion of the body **(no straps are used in Hall's sleeve, see fig.1)**.

25. As to claims 30,36, Hall discloses a compression garment as recited in claim 34, wherein the inner layer comprises a corduroy material. However, application stated on page 7 0022 that the backing can comprise any breathable, woven fabric material or any other type of breathable material such as perforated polymeric sheets. Therefore, Hall's inner layer of fabric construction **(col.5 line 45)** would consider meeting the claimed limitation.

26. **As to claims 31,37, Hall disclose** a compression garment as recited in claim 35, wherein the body comprises an outer layer secured to the inner layer, the outer layer comprising a sheet of woven fabric. However, application stated on page 5 0019 that the outer layer can comprise a flexible, washable, and breathable material. Therefore, Hall's outer layer of fabric construction **(col.5 line 45)** would consider meeting the claimed limitation.

27. **As to claims 32, 38, Hall disclose** a compression garment as recited in claim 37, further comprising a layer of polymeric foam disposed between the inner layer and the outer layer. However, applicant has stated other cushioning means including conventional padding, fabric padding such as the all in one moldable fabric can be used as an alternative to foam (page 6, 0020), and Hall teaches elastomeric cushioning layer (fig.3, 15) which is considered to meet the claimed limitation since this layer is capable of providing cushioning surface.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall US Patent 6,520,926 B2 in view of Turtzo US Patent 6,254,554 B1.

28. **As to claim 22, Turtzo teaches** a compression sleeve for treating lymphedema comprising a sleeve that receives an arm of the patient (see fig.2, arm will be enclosed near the reference object 16); and a tubular portion configured to receive a hand (see fig.2, hand will be enclosed near the reference object 20 and 26) of the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the leg sleeve of Hall in view of Turtzo in order to construct a tubular sleeve for the hand portion with the same compressive concept and constructive parts as disclosed by Hall for the purposes of providing compressive force in the arm and hand area.

29. **As to claim 23, Hall do not disclose** a compression garment as recited in claim 13, wherein the tubular sleeve has a thickness and the tubular hand portion has a thickness that is greater than the

thickness of the tubular sleeve. Since it is obvious that the thickness/diameter of the sleeve many widely vary for the treatment of the body parts, Turtzo's hand sleeve can be also be constructed with the same thickness claimed by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the leg sleeve of Hall in view of Turtzo in order to construct a tubular sleeve for the hand portion with the same compressive concept and constructive parts as disclosed by Hall and provide the sleeve with the thicknesses as claimed in claim 23 for the purposes of providing compressive force in the arm and hand area.

Claim Objections

30. Claim 13 is objected to because of the following informalities: "the backing" may be referring to "the woven fabric". Appropriate correction is required.

Conclusion

31. The prior art made of record on form PTO-892 and not relied upon teaches: US 3,892,239 (inner and outer layers, pressure projection integrally formed to the inner layer) US 5,591,121 (ribs, fig.4, 28).

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed,

and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shumaya B. Ali
Examiner
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